Systematic Review Data Repository (SRDR) Training – Example Case for Blood Pressure Targets

Welcome to Systematic Review Data Repository (SRDR)!

In this module, we will ask you to initiate a new project, create an extraction form, and extract data from one study. The goal of this exercise is to familiarize new users with the SRDR by walking through the extraction of data from one sample study into a new systematic review project. Please plan to devote 2-2.5 hours for this part of the training.

All materials for successfully completing this training are provided, including step-by-step instructions and a sample study to extract. Please read the notes below before beginning these exercises.

Notes:

- Please use **Firefox, Google Chrome, IE 7, 8, 9 or Safari** browser when using SRDR
- Throughout this exercise, information specifically designated for entry into SRDR Web forms during this exercise will be noted in *italic blue*. Feel free to cut and paste these sections into the indicated fields.
- For more detailed information on how to use the SRDR site, please refer to the SRDR user manual which can be linked through the homepage.

Log In

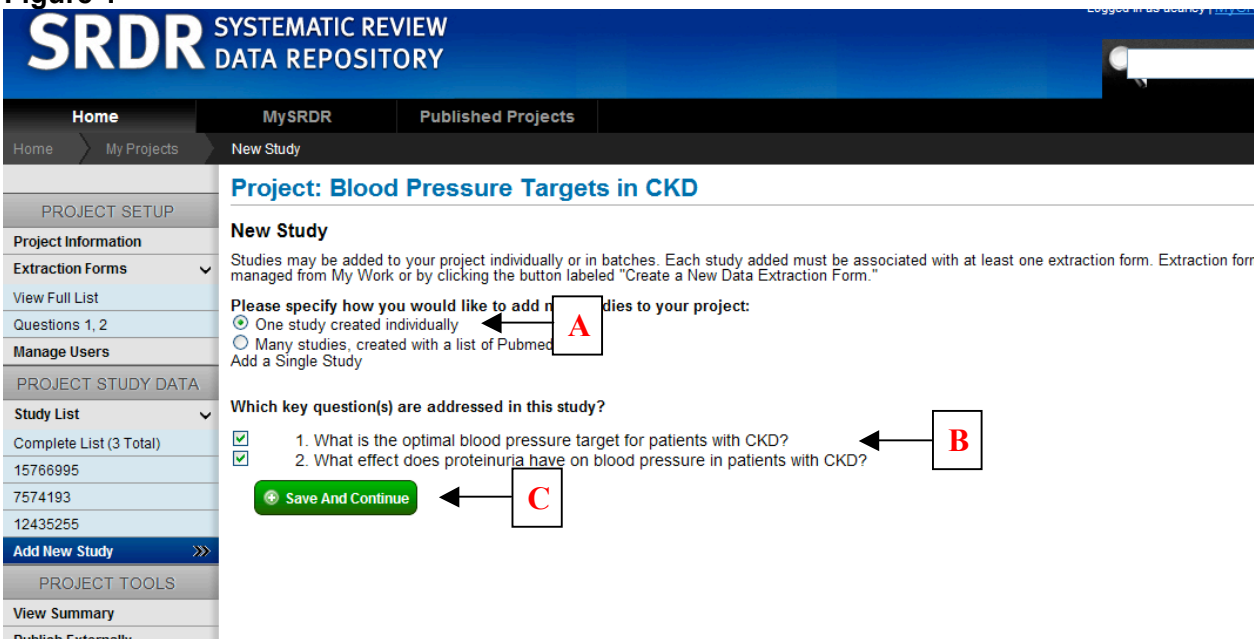
1. Go to http://srdr-dev.heroku.com/.
2. Log in using your email address as your username and the password: *cochrane*
3. Once all logged in, go to the **My SRDR** tab located under the SRDR banner.
4. Locate the project entitled **Workshop extraction**.
5. Click **Add a Study**.

A. Extract Study Data

A-1. Key questions

1. On the **New Study** page, select the first option (**One study created individually**; see item **A** in Figure 1).
2. In the resulting **Add a Single Study** dialog appearing at the bottom of the page, select Key Questions 1 and 2 by marking the appropriate check boxes (see item **B** in Figure 1).
3. Click **Save and continue** (see item **C** in Figure 1).

Figure 1



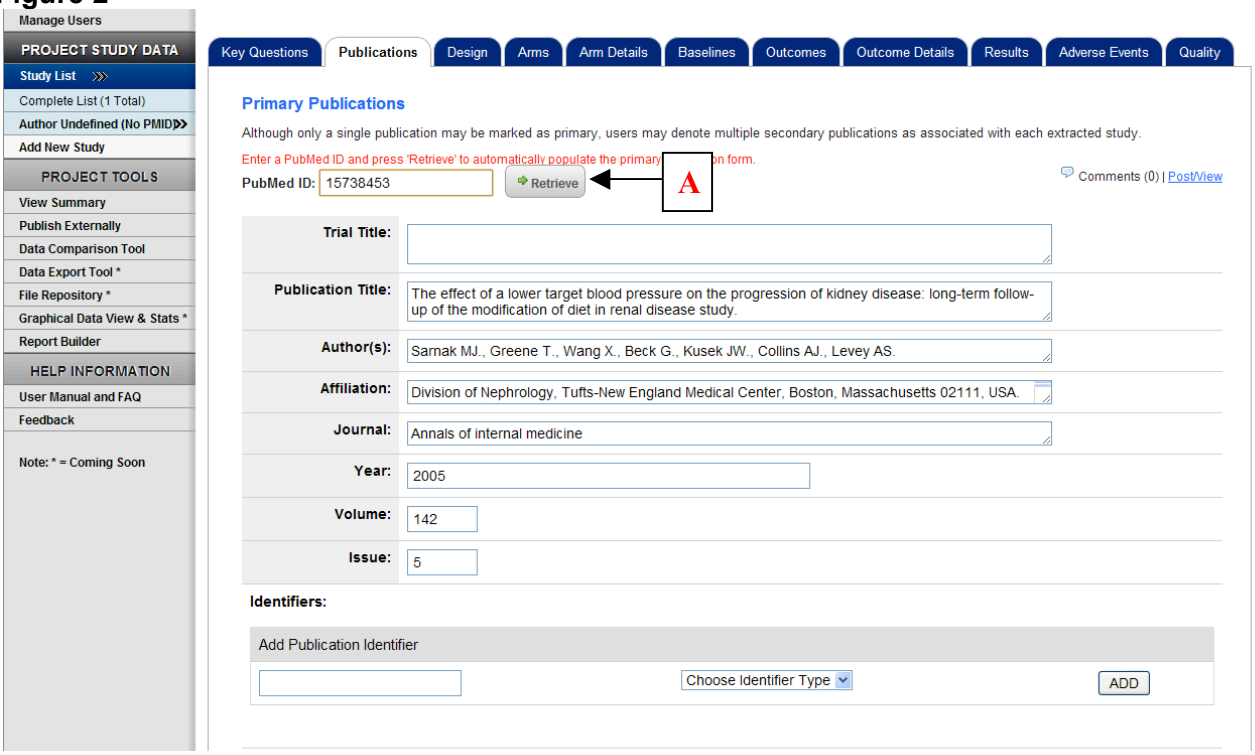
A-2. Publication

1. Enter the following **PubMed ID** into the appropriate field :

   15738453

2. Click **Retrieve** (see item **A** in Figure 2). The data fields below will be populated with information imported from PubMed.

Figure 2



3. Please review the imported information and click **Save** when finished.

4. Click **Next** or move to the next tab.

A-3. Design details

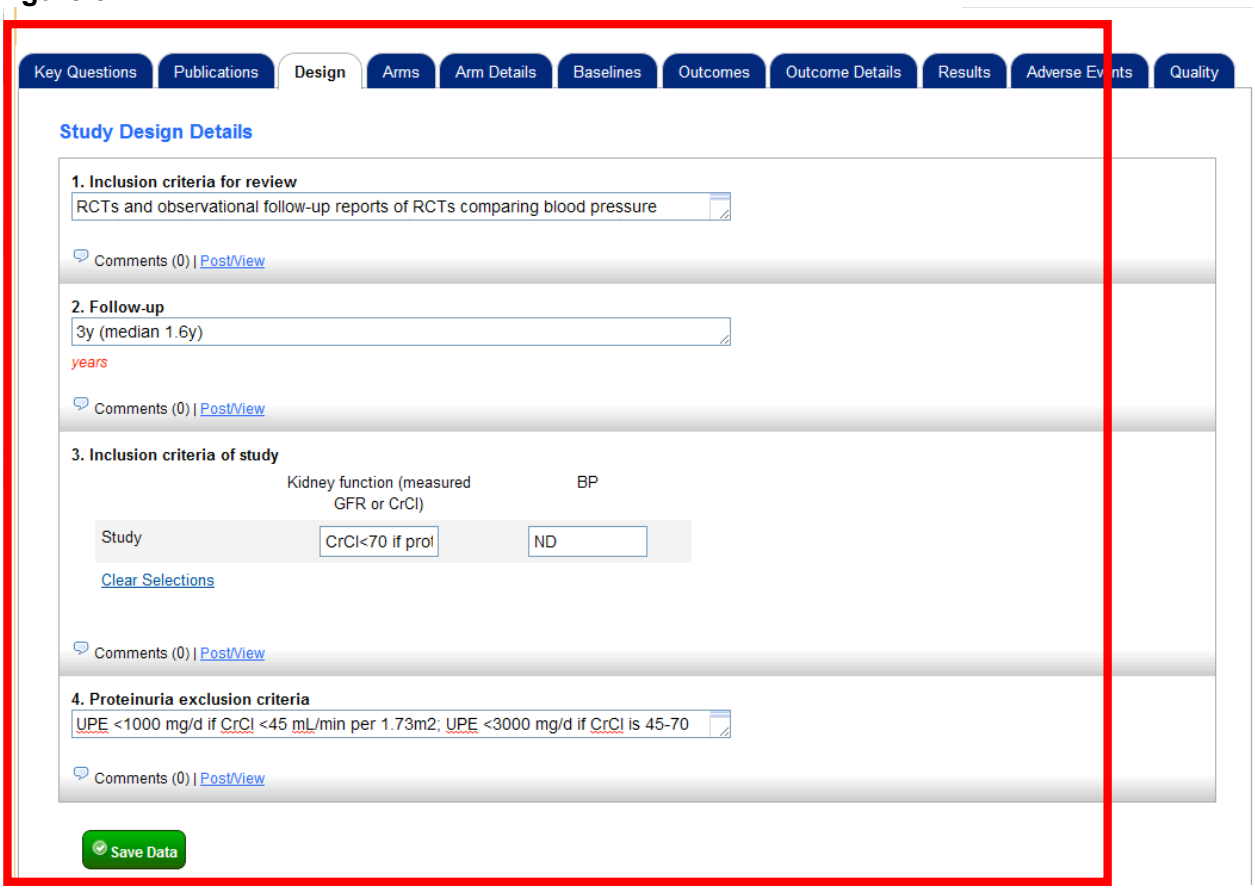
1. On the **Design Details** page, fill in the following information (see highlighted area in Figure 3):

Q#	*Question text:*	*Data to be entered:*
1	Follow up	*3 y (median 1.6y)*
2	Inclusion criteria of the study	Kidney function: *CrCl<70 if proteinuria >3000mg/d; CrCl <45 if proteinuria 1000-3000 mg/d* BP: *ND*
3	Proteinuria exclusion criteria	*UPE <1000 mg/d if CrCl <45 mL/min per 1.73m2; UPE <3000 mg/d if CrCl is 45-70 mL/min/1.73m2*

2. Please review your responses and click **Save Data** when finished.

3. Click **Next** or move to the next tab.

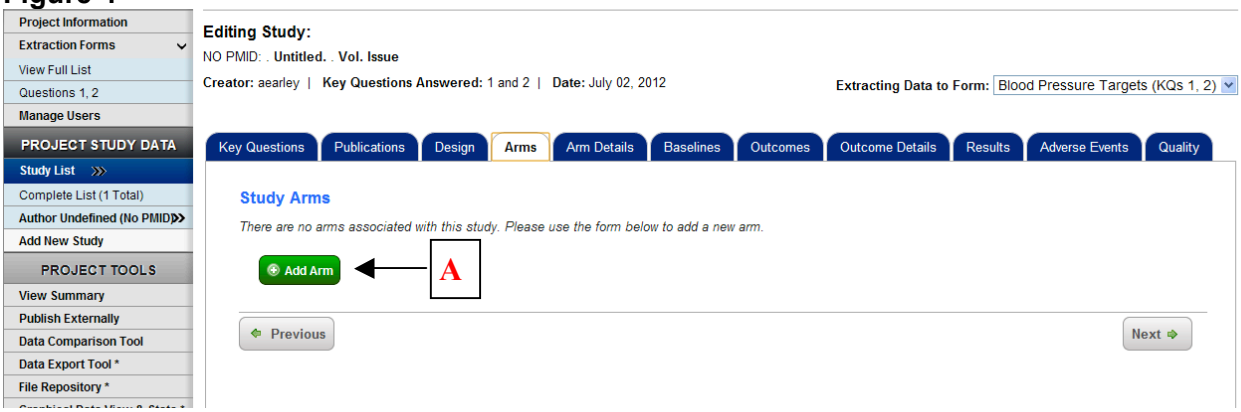
Figure 3



A-4. Study Arms

1. Click **Add Arm** (see item **A** in Figure 4).

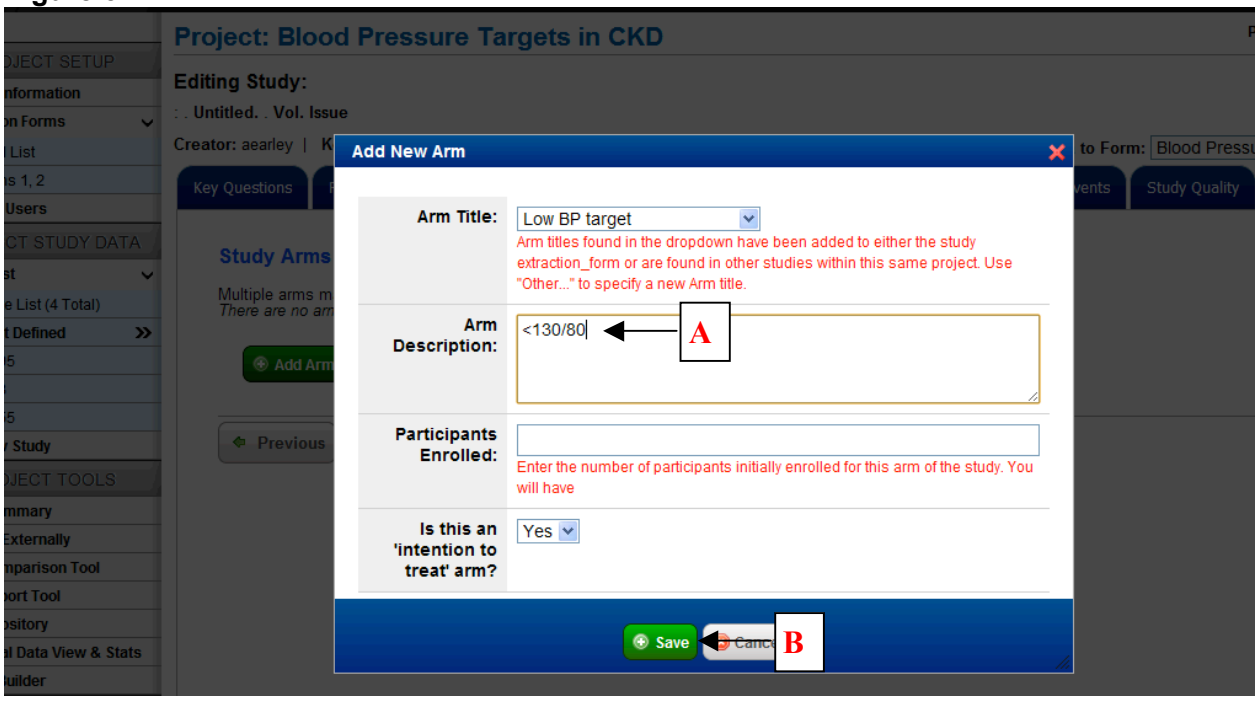
Figure 4



2. In the resulting pop-up, choose *Low BP target* from the drop-down list (see item **A** in Figure 5). In the arm description, enter *<130-80*

3. Click **Save** (see item **B** in Figure 5). The pop-up will close and the newly selected arm information will now appear in the arms table.

Figure 5

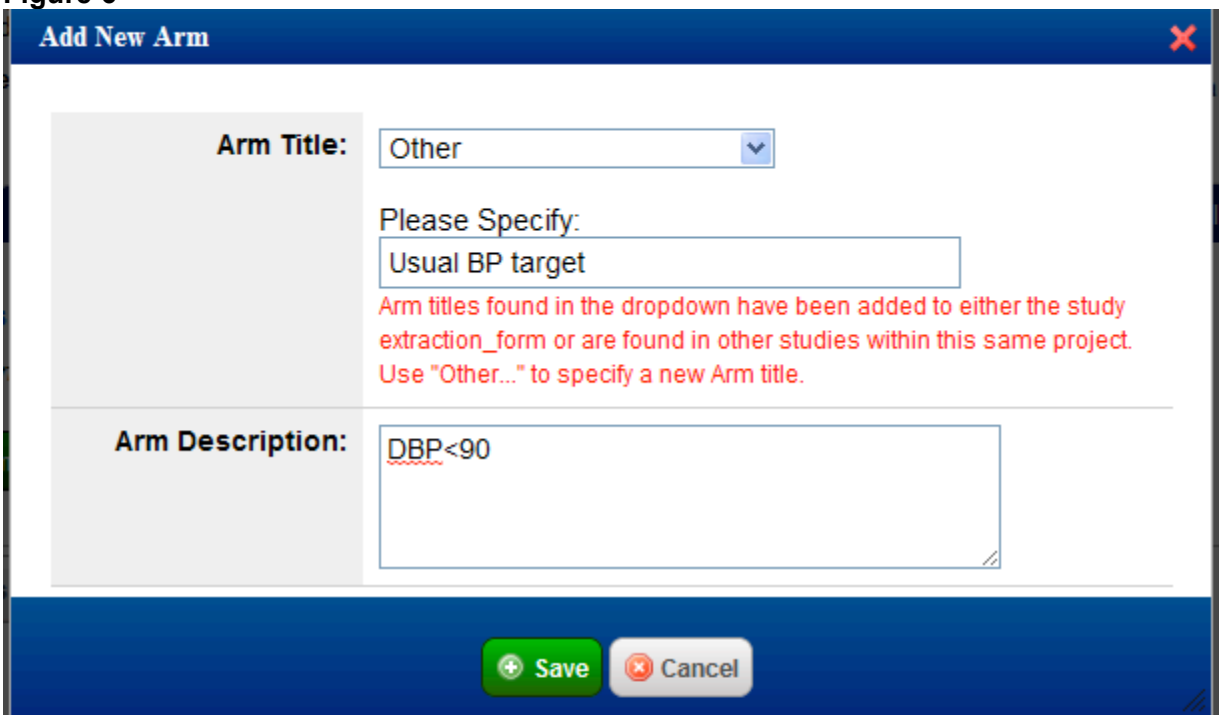


4. Click the Add Arm button again. This time you will enter an additional arm by selecting **Other** from the dropdown menu.

5. Specify the arm as *Usual BP target* and under arm description, enter *DBP <90.* (See Figure 6)

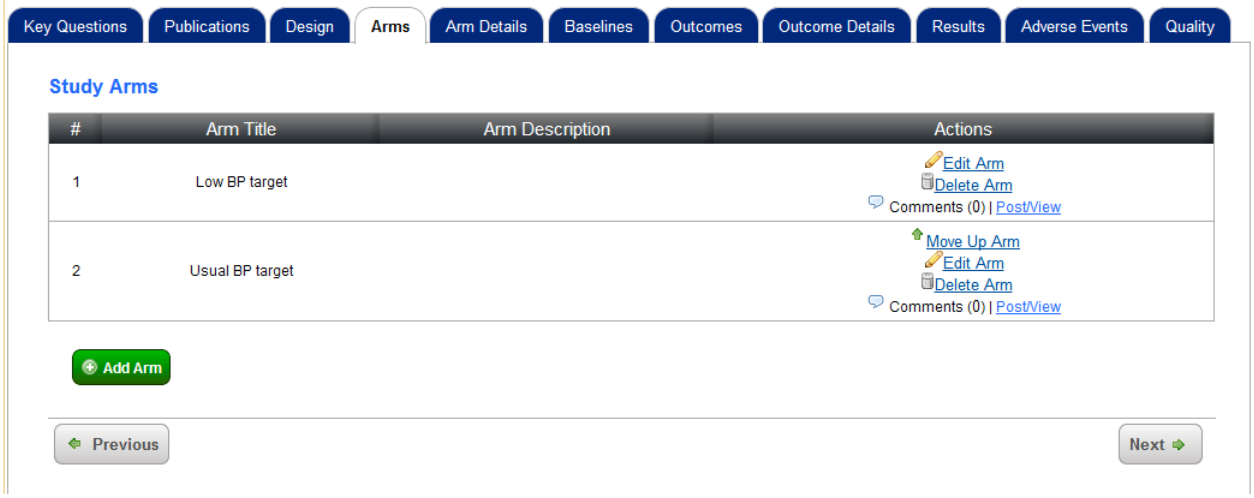
6. Please review the arms information and click **Next** or move to the next tab when finished.

Figure 6



6. Both arms will appear in the list. (see Figure 7)

Figure 7

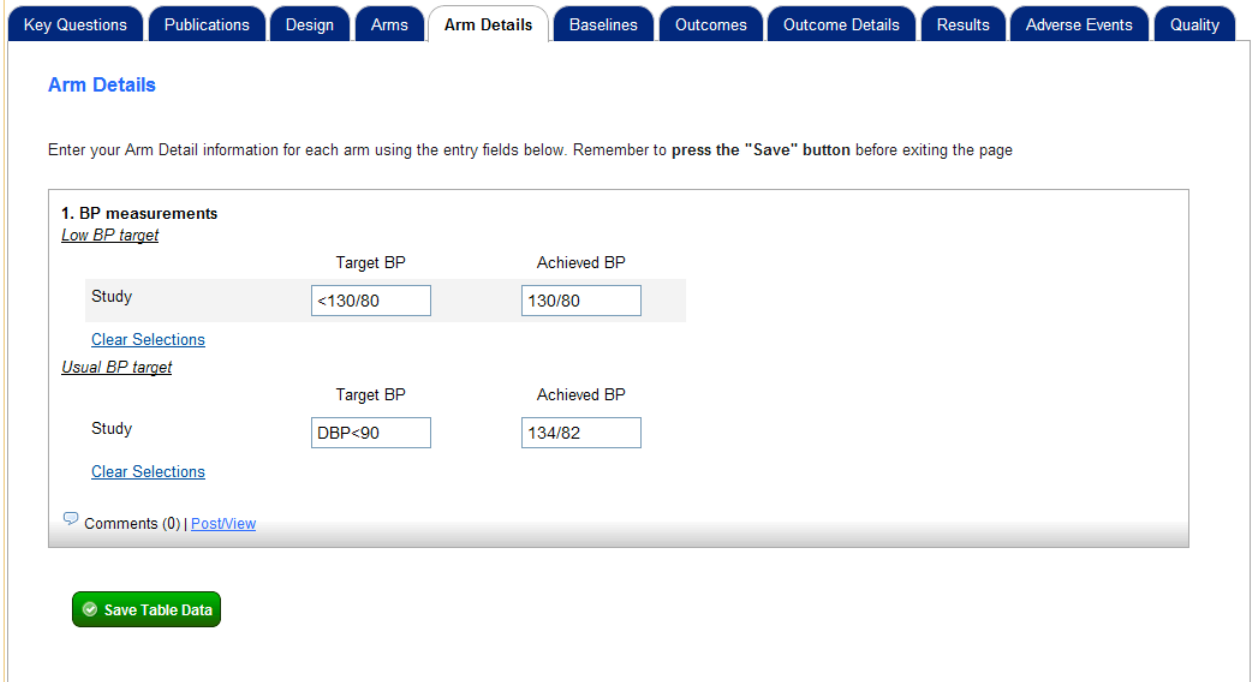


A-5. Arm Details

1. Enter in the following data (see Figure 8)

Arm	Target BP	Achieved BP
Low BP Target	*<130/80*	*130/80*
Usual BP Target	*DBP<90*	*134/82*

Figure 8



A-6. Baselines

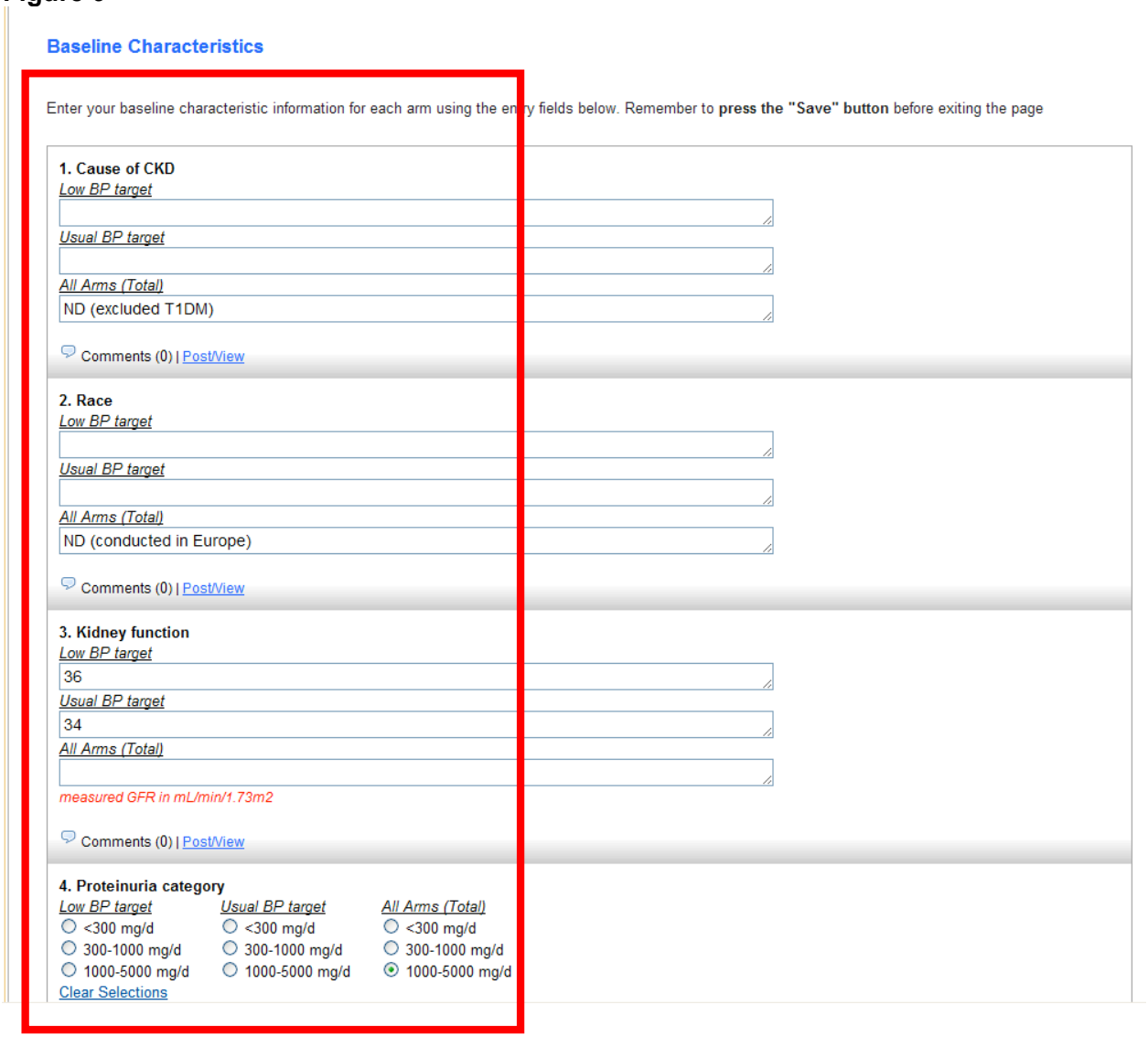
1. Enter in the following data (see Figure 9):

Q#	*Question text:*	*Data to be entered: Arm: Low BP target*	*Data to be entered: Arm: Usual BP target*	*Data to be entered: Arm: All Arms (Total)*
1	Case of CKD	*leave blank*	*leave blank*	*ND (excluded T1DM)*
2	Race	*leave blank*	*leave blank*	*ND (conducted in Europe)*
3	Kidney function	*36*	*34*	*leave blank*
4	Proteinuria category	*leave blank*	*leave blank*	*100-5000 mg/d*
5	Proteinuria criteria	*Mean: UPE 2800 mg/d SD: 2000*	*Mean: UPE 2900 mg/d SD: 1900*	*leave blank*

2. Please review your responses and click **Save Table Data** when.

3. Click **Next** or move to the next tab.

Figure 9



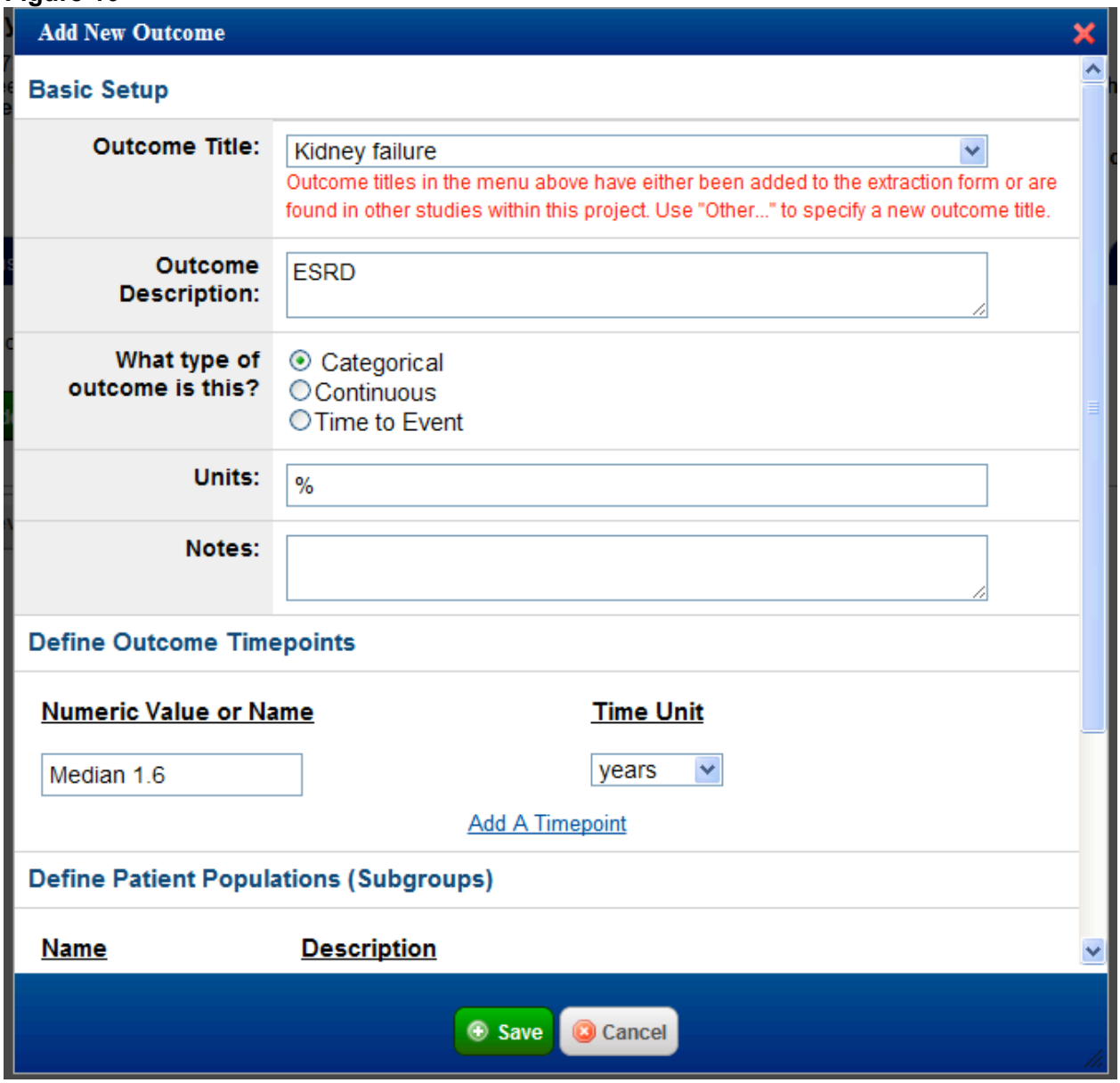
A-7. Outcome set up

1. On the **Outcome Setup** page, click **Add a New Outcome Name**.
2. In the resulting pop-up, select *Kidney failure* from the **Outcome Title** drop-down list. (See Figure 10)
3. In the **Outcome Description**, enter *ESRD.*
4. In response to **What type of outcome is this?**, select *Categorical* from the 3 options listed.
5. Enter *%* in the **Units** text box
6. In the textbox under **Define Outcome Timepoints** enter the following information

Numeric Value or Name	Time unit
3	*years*

7. Under **Define Patient Populations (Subgroups)**, click **Add A Subgroup**.
8. In the text box under **Name**, enter *Patients with baseline proteinuria ≥3g/24h.*
9. Again, click **Add A Subgroup** and enter *Patients with baseline proteinuria 1-3g/24h.*
10. Click **Save**.

Figure 10



11. Repeat steps 21-30 for the following outcome:

Outcome Title	*Mortality*
Outcome Description	*Leave blank*
What type of outcome is this?	*Categorical*
Units	*%*
Define outcome timepoints	*3 years*
Subgroups	*None (skip this step)*

12. Please review your entries and click **Next** or move to the next tab when finished.

A-8. Outcome Details

1. In this section, enter *ESRD* as the primary outcome.

2. Click **Next**

A-9.Outcome Results

In this section, you will be creating analysis tables based on the information that you have previously entered.

1. From the drop-down list labeled **Step 1. Choose the outcome and population to enter data for**, select:
   Kidney failure (from 1st drop-down) (see item **A** in Figure 11).
   And
   All Participants (from the 2nd drop-down) (see item **B** in Figure 11)

2. Within the table, click **Edit Measures** (see item **C** in Figure 11).
   a. Unselect **N Enrolled**, **Counts**, and **Standard Deviation**
   b. Select **N Analyzed** and **Percentage**
   c. Click **Save**

3. Enter the following values into the table under the appropriate arms:

	Arm: *Low BP target*	***Arm:*** *Usual BP target*
N Analyzed	*167*	*168*
Percentage	*23*	*20*
Counts	*38*	*34*

4. Click **Save Table Data**. (see item **D** in Figure 11)

5. Click on the blue box labeled **Create Between-Arm Comparisons.**

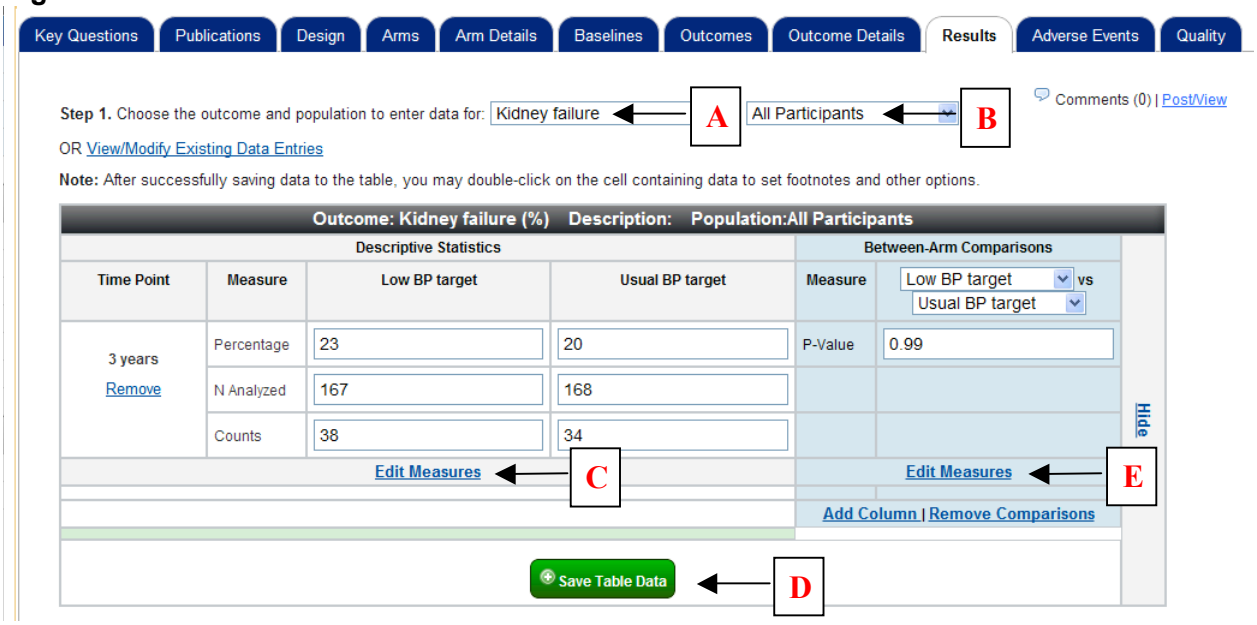
6. Within the table, click **Edit Measures**. (see item **E** in Figure 11)
   a. Unselect **Statistical test**, **Odds Ratio (OR)**, and **Standard Deviation**
   b. Select **P-Value**
   c. Click **Save**

7. From the drop-down box select, *Low BP target* vs. *Usual BP target***.**

8. Enter *0.99*

9. Click **Save Table Data**. (see item **D** in Figure 11)

Figure 11

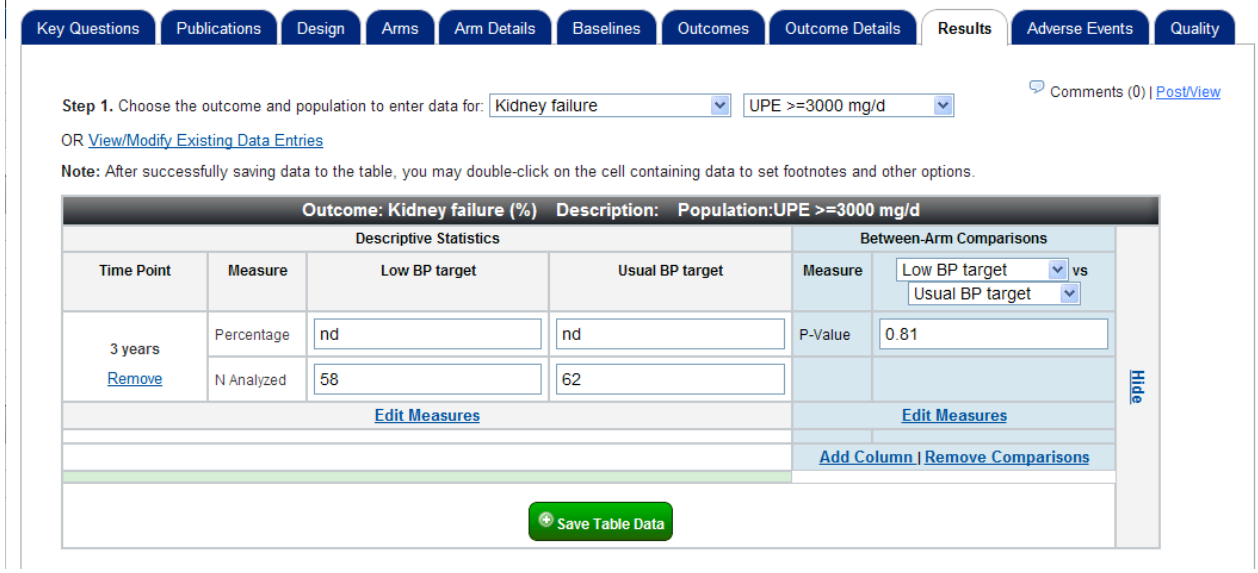


10. Now choose the subgroup for *Patients with baseline proteinuria ≥3g/24h* from the 2nd drop-down under **Step 1**.

11. Enter the following data (see Figure 12):

	Arm: *Low BP target*	***Arm:*** *Usual BP target*
N Analyzed	*58*	*62*
Percentage	*nd*	*nd*
Between Arm Comparison	*Low BP Target vs. Usual BP Target*	
P-Value	*0.81*	

Figure 12



12. Repeat for subgroup *Patients with baseline proteinuria 1-3g/24h* the following outcomes:

	Arm: *Low BP target*	***Arm:*** *Usual BP target*
N Analyzed	*109*	*106*
Percentage	*nd*	*nd*
Between Arm Comparison	*Low BP Target vs. Usual BP Target*	
P-Value	*0.89*	

13. Repeat steps 1-9 for the **Mortality** outcome entering the following data:

Outcome Mortality		
	Arm: *Low BP target*	***Arm:*** *Usual BP target*
N Analyzed	*167*	*168*
Percentage	*2*	*1*
Between-Arm comparison	*NONE (no need to enter data)*	

A-10. Adverse Events

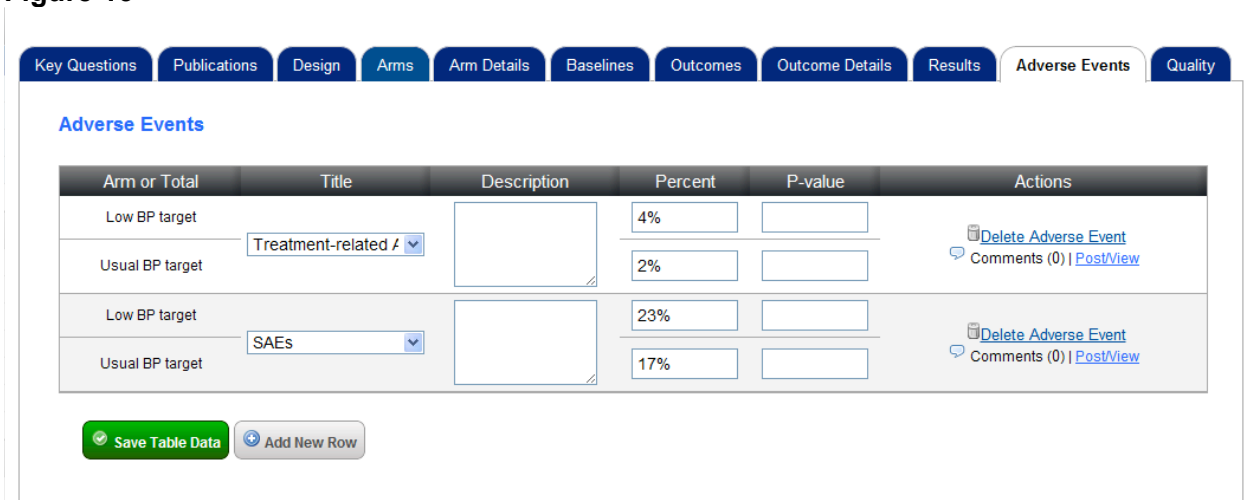
1. Click **Add New Row.**

2. In the table that appears enter the following data (see Figure 13):

Title	*Treatment-related adverse events*	
Description	*Leave blank*	
	Low BP target	**Usual BP target**
Percent	*4%*	*2%*
P-value	*leave blank*	*leave blank*
Title	*SAEs*	
Description	*Leave blank*	
	Low BP target	**Usual BP target**
Percent	*23%*	*17%*
P-Value	*Leave blank*	*Leave blank*

3. 46. Click **Save Table Data**.

Figure 13



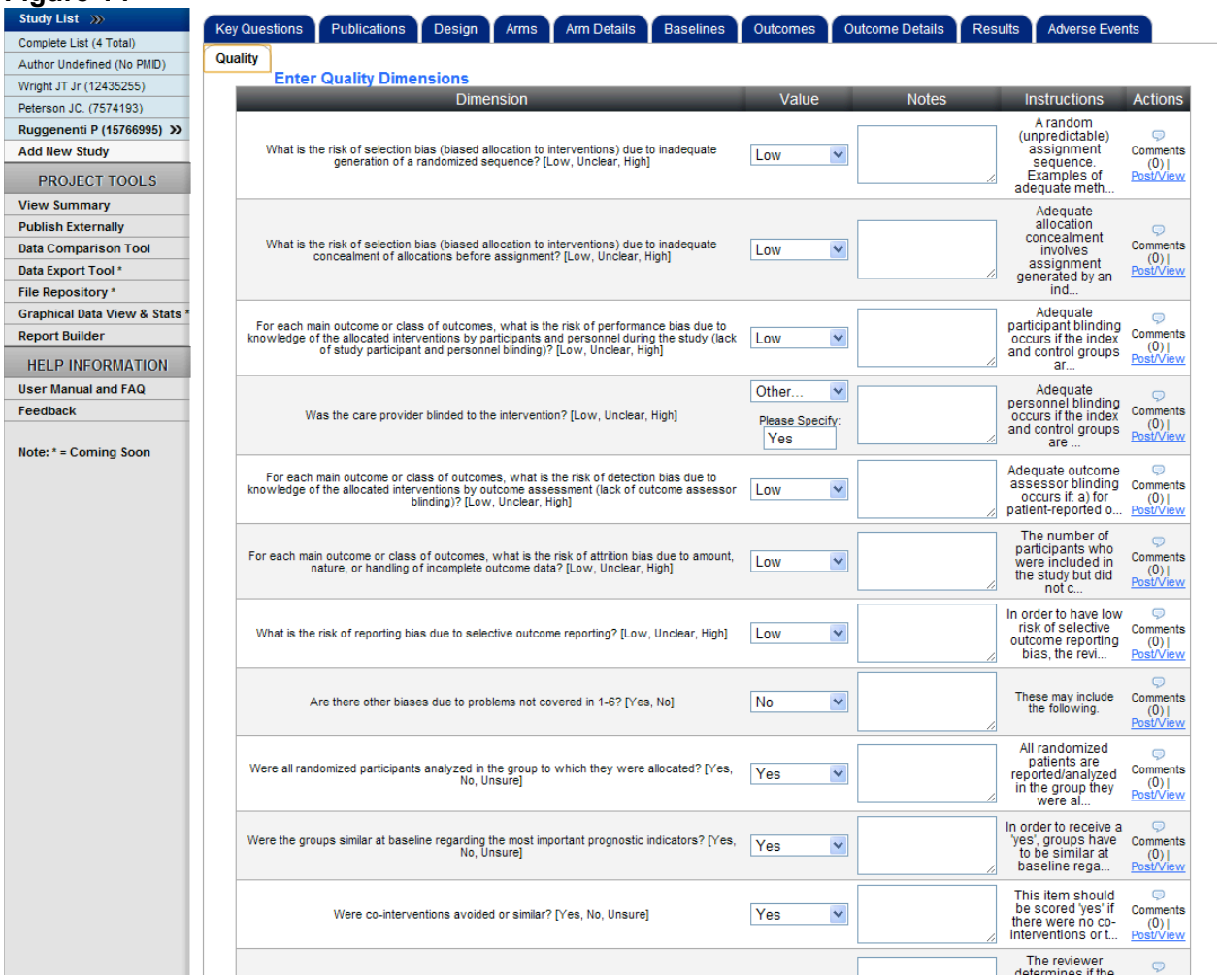
A-11. Quality

1. Select the following **Values** from the drop-down menus for each of the questions listed (see Figure 14):

1	What is the risk of selection bias (biased allocation to interventions) due to inadequate generation of a randomized sequence?	*Low*
2	What is the risk of selection bias (biased allocation to interventions) due to inadequate concealment of allocations before assignment?	*Low*
3	For each main outcome or class of outcomes, what is the risk of performance bias due to knowledge of the allocated interventions by participants and personnel during the study (lack of study participant and personnel blinding)?	*Low*
4	Was the care provider blinded to the intervention?	*Other,* Please specify: *Yes*
5	For each main outcome or class of outcomes, what is the risk of detection bias due to knowledge of the allocated interventions by outcome assessment (lack of outcome assessor blinding)?	*Low*
6	For each main outcome or class of outcomes, what is the risk of attrition bias due to amount, nature, or handling of incomplete outcome data?	*Low*
7	What is the risk of reporting bias due to selective outcome reporting?	*Low*
8	Are there other biases due to problems not covered in 1-6?	*No*
9	Were all randomized participants analyzed in the group to which they were allocated?	*Yes*
10	Were the groups similar at baseline regarding the most important prognostic indicators?	*Yes*
11	Were co-interventions avoided or similar?	*Yes*
12	Was the compliance acceptable in all groups?	*Yes*
13	Was the timing of the outcome assessment similar in all groups?	*Yes*
14	Are there other risks of bias? If yes, describe them in the Notes.	*No*

2. Please review your entries and click **Save Table Data** when finished.

Figure 14

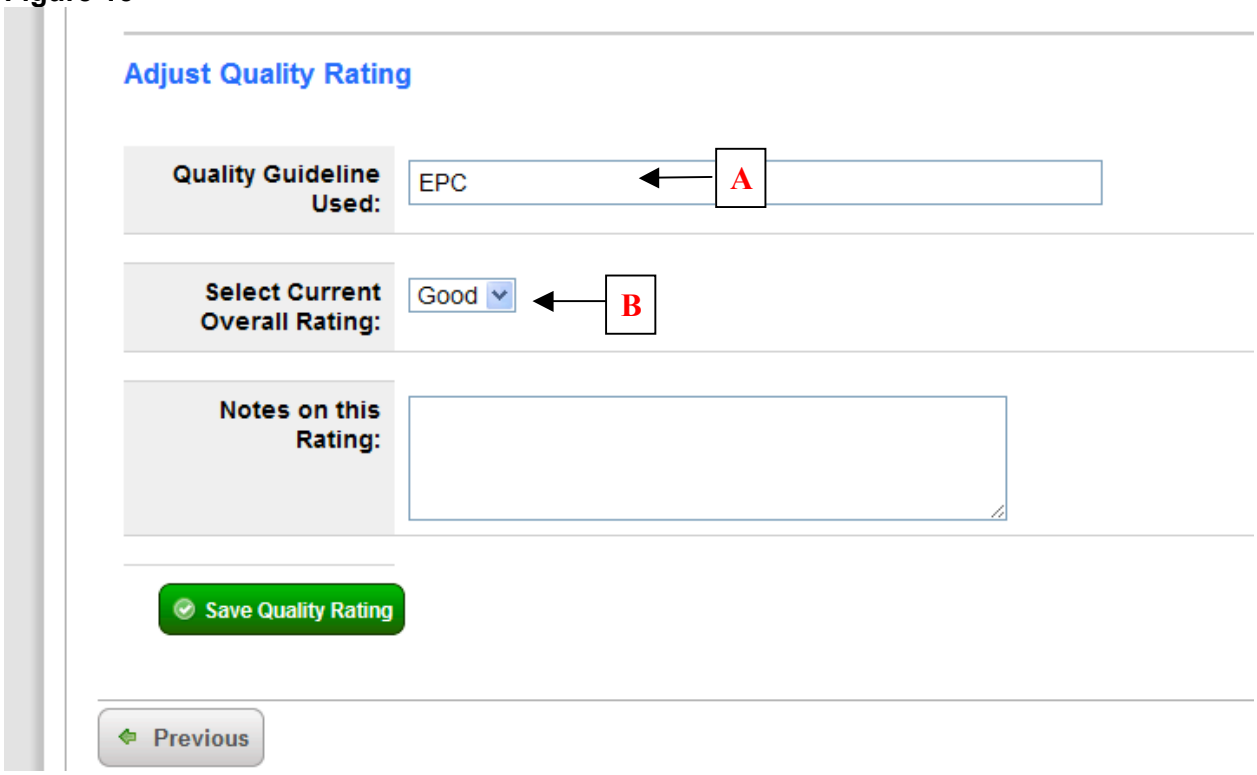


3. Scroll to the bottom of the screen and enter *EPC* in the **Quality Guideline Used** field (see item **A** in Figure 15).

4. Choose *Good* from the drop-down list labeled **Select Current Overall Rating** (see item **B** in Figure 15).

5. Click **Save Quality Rating** when finished.

Figure 15



6. Click **Save Quality Rating**.

*You have completed the **Extract Study Data** exercise*